FEB 1 4 2012

LIO-500 510(k) Summary

K113390

Submitter:

Regulatory Insight, Inc.
5401 S. Cottonwood Ct.
Greenwood Village, Colorado 80121
Contact: Mr. Kevin Walls, RAC
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for

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Device Name:

Trade Name: Laser Indirect Ophthalmoscope 500 (LIO-500)
Common Name: Ophthalmic Surgical Laser
Classification Name: Powered Laser Surgical Instrument

Predicate Device:

VISULAS 532S manufactured by CARL ZEISS, INC. and cleared under 510(k) # K013402

Device Description:

The LIO-500 can be used on a 532 nm laser such as the MERILAS 532α or any other ophthalmic laser with 532 nm.

The LIO-500 does not incorporate any contacts, displays or other user accessible functions. Its main purpose is the delivery of the laser light, generated by an ophthalmic treatment laser unit to the eye of the patient. For the observation of the treatment area the attached indirect ophthalmoscope (such as the Heine Omega 500 or the Keeler Vantage Plus / Keeler Vantage Plus LED) gets used.

Intended Uses:

The Laser Indirect Ophthalmoscope 500 (LIO-500) is intended for use in photocoagulating ocular tissue in the treatment of diseases of the eye.

The laser energy is delivered via either transpupillary delivery or intraocular endoprobe delivery.

Comparison to Predicate Device:
The LIO-500 has the same technical characteristics as the VISULAS 532S. There are no clinical or non-clinical tests required to show substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB 14 2012

Meridian AG
% Regulatory Insight, Inc.
Mr. Kevin Walls, RAC
5401 South Cottonwood Court
Greenwood Village, Colorado 80121

Re: K113390
Trade/Device Name: Lase Indirect Ophthalmoscope 500 (LIO-500)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 15, 2011
Received: November 16, 2011

Dear Mr. Walls:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113390

Device Name: Laser Indirect Ophthalmoscope 500 (LIO-500)

Indications for Use:

The Laser Indirect Ophthalmoscope 500 (LIO-500) is intended for use in photocoagulating ocular tissue in the treatment of diseases of the eye.

The laser energy is delivered via either transpupillary delivery or intraocular endoprobe delivery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neal R. Ogden for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113390